

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

UNITED STATES OF AMERICA	:	CRIMINAL NO:
v.	:	
APOTEX CORP.	:	VIOLATION: 15 U.S.C. § 1
	:	

DEFERRED PROSECUTION AGREEMENT

The United States Department of Justice, Antitrust Division (“United States”) and Apotex Corp. (“Apotex” or the “Company”), a corporation organized and existing under the laws of Delaware, by and through its undersigned representative, pursuant to authority granted by its board of directors, enter into this Deferred Prosecution Agreement, the terms and conditions of which are as follows:

Criminal Information and Acceptance of Responsibility

1. Apotex acknowledges and agrees that the United States will file a one-count criminal Information in the United States District Court for the Eastern District of Pennsylvania. The Information will charge Apotex with a single count of conspiring through certain of its current and/or former employees with other persons and entities engaged in the production and/or sale of generic drugs to suppress and eliminate competition by agreeing to increase and maintain prices of pravastatin sold in the United States, from in or about May 2013 and continuing through at least December 2015, in violation of the Sherman Antitrust Act, 15 U.S.C. § 1. In so doing, Apotex: (a) knowingly waives its right to indictment on this charge, as well as all rights to a speedy trial pursuant to the Sixth Amendment to the United States Constitution, Title 18, United States Code, Section 3161, and Federal Rule of Criminal Procedure 48(b); and (b) knowingly waives for the

purposes of this Agreement and for the purposes of any charges by the United States arising out of the conduct described in the Statement of Facts (attached hereto as Attachment A and incorporated by reference into this Agreement) any objection with respect to venue and consents to the filing of the Information, as provided under the terms of this Agreement, in the United States District Court for the Eastern District of Pennsylvania. The United States agrees to defer prosecution of Apotex pursuant to the terms and conditions described below.

2. Apotex acknowledges that, under United States law, it is responsible for the acts of certain of its current and/or former employees that give rise to the charges in the Information. Apotex admits, accepts, and acknowledges that the facts set forth in the Statement of Facts are true and accurate. Should the United States pursue the prosecution that is deferred by this Agreement, Apotex agrees that it will neither contest the admissibility of, nor contradict, any of the facts set forth in the Statement of Facts in any such proceeding, including any guilty plea or sentencing proceeding. Neither this Agreement nor the criminal Information is a final adjudication of the matters addressed in such documents.

Parties to and Scope of the Agreement

3. Apotex is organized under the laws of Delaware with its principal place of business in Florida. This Agreement binds Apotex and the United States Department of Justice Antitrust Division. It specifically does not bind any other component of the Department of Justice, other federal agencies, or any state, local, or foreign law enforcement or regulatory agencies, or any other authorities. This Agreement also creates contingent rights and obligations for Apotex's current officers, directors, and employees as of the date of the signature of this Agreement, who

will be collectively referred to as “Covered Individuals.” The contingent rights and obligations for Covered Individuals are limited expressly as described below.

Length of the Agreement

4. This Agreement is effective for a period beginning on the date on which the Information is filed and ending three (3) years from that date (the “Term”), except for the obligations set forth in Paragraphs 6–7 below. Apotex agrees that in the event that the United States determines, in its sole discretion, that Apotex has violated any provision of this Agreement, an extension or extensions of the term of the Agreement may be imposed by the United States, in its sole discretion, for up to a total additional time period of one year, without prejudice to the United States’ right to proceed as provided in Paragraphs 17–21 below. Any extension of the Agreement extends all terms of this Agreement for an equivalent period.

Relevant Considerations

5. The United States enters into this Agreement based on the individual facts and circumstances of this case. Among the facts considered were the following: (a) a conviction (including a guilty plea) would likely result in Apotex’s mandatory exclusion from all federal health care programs under 42 U.S.C. § 1320a-7 for a period of at least five years, which would result in substantial consequences to the corporation’s employees and customers outside the federal health care programs; (b) Apotex timely agreed to cooperate in the United States’ ongoing investigation into criminal antitrust violations among generic drug manufacturers; (c) Apotex’s cooperation will aid the United States’ investigation into criminal antitrust conspiracies among other manufacturers of generic drugs; (d) Apotex’s cooperation remains ongoing; and (e) this Agreement can ensure that integrity has been restored to Apotex’s operations and preserve its

financial viability while preserving the United States' ability to prosecute it should material breaches occur.

Cooperation Obligations

6. Until the date upon which all investigations and prosecutions, whether of former employees of the Company or other individuals or entities, arising out of the conduct described in this Agreement are concluded, whether or not they are concluded within the three-year period specified in paragraph 4, Apotex shall cooperate fully and truthfully with the United States in the current federal criminal investigation of violations of federal antitrust and related criminal laws involving the production and sale of generic drugs in the United States, and any criminal litigation or other criminal proceedings arising or resulting from such investigation to which the United States is a party (collectively "Federal Criminal Proceeding"). The Federal Criminal Proceeding includes, but is not limited to, a criminal investigation, prosecution, litigation, or other proceeding regarding obstruction of, the making of a false statement or declaration in, the commission of perjury or subornation of perjury in, the commission of contempt in, or conspiracy to commit such offenses in the current federal criminal investigation of violations of federal antitrust and related criminal laws involving the production and sale of generic drugs in the United States. The full, truthful, and continuing cooperation of Apotex will include but not be limited to:

(a) producing to the United States all documents, information, and other materials, wherever located, not protected under the attorney-client privilege or the work-product doctrine, and with translations into English, in the possession, custody, or control of Apotex, that are requested by the United States in connection with the Federal Criminal Proceeding; and

(b) using its best efforts to secure the full, truthful, and continuing cooperation of the Covered Individuals as may be requested by the United States. Such efforts will include, but not be limited to, making these persons available in the United States and at other mutually agreed-upon locations at Apotex's expense for interviews and the provision of testimony in grand jury, trial, and other judicial proceedings in connection with the Federal Criminal Proceeding.

7. The full, truthful, and continuing cooperation of Covered Individuals will be subject to the procedures and protections of this paragraph, and will include, but not be limited to:

(a) producing in the United States and at other mutually agreed-upon locations, not at the expense of the United States, all documents, including claimed personal documents, and other materials, wherever located, not protected under the attorney-client privilege or the work-product doctrine, and with translations into English, that are requested by attorneys and agents of the United States in connection with the Federal Criminal Proceeding;

(b) being available for interviews in the United States and at other mutually agreed-upon locations, not at the expense of the United States, upon the request of attorneys and agents of the United States in connection with the Federal Criminal Proceeding;

(c) responding fully and truthfully to all inquiries of the United States in connection with the Federal Criminal Proceeding, without falsely implicating any person or intentionally withholding any information, subject to the penalties of making a false statement or declaration (18 U.S.C. §§ 1001, 1623), obstruction of justice (18 U.S.C. § 1503 *et seq.*), or conspiracy to commit such offenses;

(d) otherwise voluntarily providing to the United States any material or information not requested in (a)–(c) of this paragraph and not protected under the attorney-client privilege or work-product doctrine that he or she may have that is related to the Federal Criminal Proceeding;

(e) when called upon to do so by the United States in connection with the Federal Criminal Proceeding, participating in affirmative investigative techniques, including but not limited to making telephone calls, recording conversations, and introducing law enforcement officials to other individuals, with all such activity being conducted only at the express direction and under the supervision of attorneys and agents of the United States;

(f) when called upon to do so by the United States in connection with the Federal Criminal Proceeding, testifying in grand jury, trial, and other judicial proceedings in the United States fully, truthfully, and under oath, subject to the penalties of perjury (18 U.S.C. § 1621), making a false statement or declaration in grand jury or court proceedings (18 U.S.C. § 1623), contempt (18 U.S.C. §§ 401–402), and obstruction of justice (18 U.S.C. § 1503 *et seq.*); and

(g) agreeing that, if the agreement not to prosecute him or her pursuant to this Agreement is void, the statute of limitations period for any offense will be tolled for the period between the date of signature of this Agreement and six months after the date that the United States gave notice of its intent to void its obligations to that person under this Agreement.

Nothing in Paragraph 7 creates any obligations by or for any person who is not a Covered Individual.

8. In addition to the obligations described above, during the Term of the Agreement, should Apotex learn of credible evidence or allegations of criminal violations of United States law affecting the competitive process by Apotex, or by any present or former officers, directors, employees, or agents, Apotex shall promptly report such evidence or allegations to the United States. Any information that Apotex thus discloses to the United States will likely include proprietary, financial, confidential, and competitive business information. Public disclosure of the information and reports could discourage cooperation, impede pending or potential government investigations, and thus undermine the United States' objectives in obtaining such reports. For these reasons, among others, the information and reports and the contents thereof are intended to remain and shall remain nonpublic, except as otherwise agreed to by the parties in writing, or except to the extent that the United States determines in its sole discretion that disclosure would be in furtherance of its discharge of its duties and responsibilities or is otherwise required by law.

Penalty and Restitution

9. The United States and Apotex agree that Apotex will pay a monetary penalty in the amount of \$24.1 million to the United States Treasury. Apotex must pay this sum within thirty (30) days of acceptance of this Agreement to the United States District Court for the Eastern District of Pennsylvania. Apotex and the United States agree that this penalty is appropriate given the facts and circumstances of this case, including the Relevant Considerations described in Paragraph 5.

10. The penalty set forth in Paragraph 9 is final and shall not be refunded. Furthermore, nothing in this Agreement shall be deemed an agreement by the United States that \$24.1 million is the maximum penalty that may be imposed in any future prosecution in the event of a breach of this Agreement, and the United States is not precluded from arguing in any future prosecution that

the Court should impose a higher fine, although the United States agrees that under those circumstances, it will recommend to the Court that any amount paid under this Agreement should be offset against any fine the Court imposes as part of a future judgment. Apotex acknowledges that no tax deduction may be sought, and agrees that no tax deduction will be sought, in the United States in connection with the payment of any part of this penalty.

11. In light of the availability of civil causes of action, and civil cases already filed against Apotex, including the multidistrict litigation *In Re: Generic Pharmaceuticals Pricing Antitrust Litigation*, Case No. 2:16-md-2724, consolidated in the United States District Court for the Eastern District of Pennsylvania, this Agreement does not include any provision for restitution.

Conditional Release from Liability

12. In return for the full and truthful cooperation of Apotex, and compliance with the other terms and conditions of this Agreement:

(a) The United States agrees that, except as provided by this Agreement, it will not bring criminal charges against Apotex for any act or offense committed before the date of signature of this Agreement, in furtherance of an antitrust conspiracy involving the production or sale of generic drugs in the United States.

(b) The United States further agrees that, except as provided by this Agreement, it will not bring criminal charges against any Covered Individual for any act or offense committed before the date of signature of this Agreement, in furtherance of an antitrust conspiracy involving the production or sale of generic drugs in the United States, provided that at the time of the conduct, (i) the Covered Individual was employed by Apotex, (ii) the Covered Individual was acting within the scope of his or her responsibilities at Apotex, and (iii) the Covered Individual's actions were at least in part in Apotex's interests.

(c) Failure by any person or the Company to comply fully with his, her, or its cooperation obligations under Paragraphs 6–8 will void the United States’ agreement in Paragraphs 12(a) and (b), and any such person or the Company may be prosecuted criminally for any federal crime of which the United States has knowledge.

(d) The United States’ agreement in Paragraphs 12(a) and (b) does not apply to subornation of perjury (18 U.S.C. § 1622), false statements (18 U.S.C. § 1001), obstruction of justice (18 U.S.C. § 1503 *et seq.*), contempt (18 U.S.C. §§ 401–402), or conspiracy to commit such offenses. Its agreement in Paragraphs 12(a) and (b) also does not apply to civil matters of any kind, any civil or criminal violation of the federal tax or securities laws or conspiracy to commit such offenses, or any crimes of violence.

Related Administrative Proceedings

13. Apotex understands that it may be subject to suspension or debarment action by state or federal agencies other than the United States Department of Justice, Antitrust Division based upon this Agreement, and that this Agreement in no way controls what action, if any, other agencies may take. However, the United States agrees that, if requested, it will advise the appropriate officials of any governmental agency considering such action of the fact, manner, and extent of the cooperation of Apotex as a matter for that agency to consider before determining what action, if any, to take.

Corporate Compliance Program

14. Apotex represents that it has implemented and will continue to implement a compliance program designed to prevent and detect criminal antitrust violations throughout its operations. Implementation of these policies and procedures shall not be construed in any future enforcement proceeding as providing immunity or amnesty for any crimes not disclosed to the

Antitrust Division as of the date of this Agreement for which Apotex would otherwise be responsible.

Deferred Prosecution

15. In consideration of: (a) the future cooperation of Apotex described in Paragraphs 6–8; and (b) Apotex’s payment of a monetary penalty, the United States agrees that any prosecution of Apotex for the conduct set forth in the attached Statement of Facts be and hereby is deferred for the Term of this Agreement.

16. The United States further agrees that if Apotex fully complies with all obligations under this Agreement, the United States will not continue the criminal prosecution of Apotex described in Paragraph 1 and, at the conclusion of the Term, this Agreement shall expire, except for the Cooperation Obligations provided in Paragraphs 6–7. Within thirty (30) days of the Agreement’s expiration, the United States shall seek dismissal with prejudice of the criminal Information described in Paragraph 1.

Breach

17. If, during the Term of this Agreement, the United States determines, in its sole discretion, that Apotex (a) committed any felony under United States federal law subsequent to the signing of this Agreement, (b) at any time provided to the United States in connection with this Agreement deliberately false, incomplete, or misleading information, including in connection with its disclosure of information about individual culpability, (c) fails to cooperate as set forth in Paragraphs 6–8 of this Agreement, or (d) otherwise breached the Agreement, Apotex shall thereafter be subject to prosecution for any federal criminal violation related to the marketing and sale of generic drugs in the United States of which the United States has knowledge, including the charges in the Information described in Paragraph 1, which may be pursued by the United States in the United States District Court for the Eastern District of Pennsylvania or any other appropriate

venue. Any such prosecution may be premised on information provided by Apotex, or its current or former officers, directors, employees, or agents. Any such prosecution that is not time barred by the applicable statute of limitations on the date of the signing of this Agreement may be commenced against Apotex notwithstanding the expiration of the statute of limitations between the signing of this Agreement and the expiration of the Term plus one year. Thus, by signing this Agreement, Apotex agrees that the statute of limitations with respect to any such prosecution that is not time barred on the date of the signing of this Agreement shall be tolled for the Term plus one year.

18. In the event that the United States determines that Apotex has breached this Agreement, the United States agrees to provide Apotex with written notice of such breach prior to instituting any prosecution resulting from such breach. Apotex shall, within thirty (30) days of receipt of such notice, have the opportunity to respond to the United States in writing to explain the nature and circumstances of such breach, as well as the actions Apotex has taken to address and remediate the situation, which explanation the United States shall consider in determining whether to institute a prosecution.

19. In the event that the United States determines that Apotex has breached this Agreement: (a) all statements made by or on behalf of Apotex to the United States or to the Court, including the attached Statement of Facts, and any testimony given by Apotex before a grand jury, a court, or any tribunal, or at any legislative hearings, whether prior or subsequent to this Agreement, and any leads derived from such statements or testimony, shall be admissible in evidence in any and all criminal proceedings brought by the United States against Apotex; and (b) Apotex shall not assert any claim under the United States Constitution, Rule 11(f) of the Federal Rules of Criminal Procedure, Rule 410 of the Federal Rules of Evidence, or any other federal law

or rule that statements made by or on behalf of Apotex prior or subsequent to this Agreement, or any leads derived therefrom, should be suppressed. The decision whether the conduct or statements of any current director or employee, or any person acting on behalf of, or at the direction of, Apotex will be imputed to Apotex for the purpose of determining whether Apotex has breached any provision of this Agreement shall be in the sole discretion of the United States.

20. Apotex acknowledges that the United States has made no representations, assurances, or promises concerning what sentence may be imposed by the Court if Apotex breaches this Agreement and this matter proceeds to judgment. Apotex further acknowledges that any such sentence is solely within the discretion of the Court and that nothing in this Agreement binds or restricts the Court in the exercise of such discretion.

21. On the date that the period of deferred prosecution specified in this Agreement expires or on the first business day thereafter, Apotex, by the President of the Company, will certify to the United States that Apotex has met its disclosure obligations pursuant to Paragraph 8 of this Agreement. The certification will be deemed a material statement and representation by Apotex to the executive branch of the United States for purposes of 18 U.S.C. §§ 1001 and 1519, and it will be deemed to have been made in the judicial district in which this Agreement is filed.

Sale or Merger of Apotex

22. Apotex agrees that in the event that it undertakes any change in corporate form, including if it sells, merges, or transfers business operations that are material to its consolidated operations, as they existed as of the date of this Agreement, whether such sale is structured as a sale, asset sale, merger, transfer, or other change in corporate form, it shall include in any contract for sale, merger, transfer, or other change in corporate form a provision binding the purchaser, or any successor in interest thereto, to the obligations described in this Agreement. The cooperation

obligations of any acquiring company as applicable under this paragraph shall be coextensive with Apotex's cooperation obligations as of the date of this Agreement. Such acquisition will neither create additional, nor limit in any way, required cooperation obligations. The purchaser or successor in interest must also agree in writing that the United States' ability to enforce all provisions of this Agreement, including to determine that it has been breached, is applicable in full force to that entity. Apotex agrees that the failure to include these provisions in the transaction will make any such transaction null and void. Apotex shall provide notice to the United States at least thirty (30) days prior to undertaking any such sale, merger, transfer, or other change in corporate form. The United States shall notify Apotex prior to such transaction (or series of transactions) if it determines that the transaction(s) will have the effect of circumventing or frustrating the enforcement purposes of this Agreement. If at any time during the Term Apotex engages in a transaction(s) that has the effect of circumventing or frustrating the purposes of this Agreement, the United States may deem it a breach of this Agreement pursuant to Paragraphs 17–21 of this Agreement. Nothing herein shall restrict Apotex from indemnifying (or otherwise holding harmless) the purchaser or successor in interest for penalties or other costs arising from any conduct that may have occurred prior to the date of the transaction, so long as such indemnification does not have the effect of circumventing or frustrating the purposes of this Agreement, as determined by the United States.

Public Statements by Apotex

23. Apotex expressly agrees that it shall not, through present or future attorneys, officers, directors, employees, agents or any other person authorized to speak for Apotex, make any public statement, in litigation or otherwise, contradicting the acceptance of responsibility by Apotex set forth above or any of the facts set forth in the Statement of Facts. Any such

contradictory statement shall, subject to cure rights of Apotex described below, constitute a breach of this Agreement and Apotex thereafter shall be subject to prosecution as set forth in this Agreement. The decision whether any public statement by any such person contradicting a fact contained in the Statement of Facts will be imputed to Apotex for the purpose of determining whether it has breached this Agreement shall be at the sole discretion of the United States. If the United States determines that a public statement by any such person contradicts in whole or in part any fact(s) set forth in the Statement of Facts, the United States shall so notify Apotex, and Apotex may avoid a breach of this Agreement by publicly repudiating such statement(s) within five (5) business days after notification. Apotex shall be permitted to raise defenses and to assert affirmative claims in other proceedings relating to the matters set forth in the Statement of Facts provided that such defenses and claims do not contradict, in whole or in part, any fact(s) set forth in the Statement of Facts. This Paragraph does not apply to any statement made by any present or former officer, director, employee, or agent of Apotex in the course of any criminal, regulatory, or civil case initiated against such individual, unless such individual is speaking on behalf of Apotex.

24. Apotex agrees that if it or anyone speaking on behalf of Apotex issues a press release or holds any press conference in connection with this Agreement, Apotex shall first consult the United States to determine (a) whether the text of the release or proposed statements at the press conference are true and accurate with respect to matters between the United States and Apotex; and (b) whether the United States has no objection to the release. Statements at any press conference concerning this matter shall be consistent with such a press release.

Notice

25. Any notice to the United States under this Agreement shall be given by personal, overnight delivery by a recognized delivery service, or registered or certified mail, addressed to

Carsten Reichel, 450 5th Street NW, Suite 11300, Washington, DC 20530. Any notice to Apotex under this Agreement shall be given by personal, overnight delivery by a recognized delivery service, or registered or certified mail, addressed to Roberta Loomar, General Counsel of Apotex Corp., at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326, with a copy to its attorneys, Steven Cherry and April Williams, Wilmer Cutler Pickering Hale and Dorr LLP, 1875 Pennsylvania Avenue, NW, Washington, DC 20006, and James Matthews, Foley & Lardner LLP, 111 Huntington Avenue, Suite 2500, Boston, MA 02199. Notice shall be effective upon actual receipt by the United States or Apotex.


Complete Agreement

26. This Agreement and its attachment set forth all the terms of this Deferred Prosecution Agreement between Apotex and the United States. No amendments, modifications or additions to this Agreement shall be valid unless they are in writing and signed by the United States, the attorneys for Apotex, and a duly authorized representative of Apotex.


DATED: 5/7/20

Respectfully submitted,

BY: Roberta Loomar
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United States Attorney

BY: James W. Matthews
James W. Matthews
Foley & Lardner LLP
Counsel for Apotex Corp.

Attachment A: Statement of Facts

From in or about May 2013 and continuing through at least December 2015 (the “Relevant Period”), Apotex Corp. (“Apotex”), a corporation organized and existing under the laws of Delaware with its principal place of business in Weston, Florida, was engaged in the marketing and/or sale of generic drugs.

During the Relevant Period, Apotex, through certain of its current and/or former employees, conspired with other persons and entities engaged in the sale of generic drugs to suppress and eliminate competition by agreeing to increase and maintain prices of pravastatin sold in the United States. Apotex’s relevant sales of pravastatin totaled at least \$105,000,000.

During the Relevant Period, pravastatin sold by one or more conspirators, as well as payments for pravastatin, traveled in interstate commerce. The business activities of Apotex and its co-conspirators in connection with the production and/or sale of pravastatin affected by this conspiracy were within the flow of, and substantially affected, interstate trade and commerce. Pravastatin affected by the activities of Apotex and its co-conspirators was sold to customers in this District.